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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/561,484 | 12/20/2005 | Shamkant Anant Patkar | 10356.204-US | 2288 |

25908 7590 07/09/2008

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| EXAMINER | |
|---|---|
| FRONDA, CHRISTIAN L | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/09/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/561,484 | PATKAR ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTIAN L. FRONDA | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 21-31 are pending in the application.

2. Applicant's election with traverse of Group I in the reply filed on 04/16/2008 is acknowledged. Upon further consideration and in view of applicants' arguments filed on 04/16/2008, the restriction requirement has been withdrawn.

3. Claims 21-31 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 101*

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 21-30 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated polypeptide". See MPEP 2105.

## *Claim Rejections - 35 U.S.C. § 112, First Paragraph*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are directed toward the current USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

The claims are genus claims encompassing a genus of polypeptides having phospholipase activity comprising an amino acid sequence having at least 50%, 60%, 70%, 80%, 90%, 95%, and 98% sequence identity to SEQ ID NO: 1. The scope of the genus includes many members with widely differing amino acid and structures, where the genus is highly variable because a significant number of structural and biological differences between genus members exists.

The claimed polypeptides having an amino acid sequence with the recited amino acid sequence identities represent a partial structure. There is no teaching in the specification regarding which amino acids residues can be altered in SEQ ID NO: 1 (e.g. amino acid substitutions, deletions, additions, and combinations thereof), other than the variants 1-26 stated in the specification on pages 5-6, while retaining phospholipase activity. Thus, one of ordinary skill in the art would not be able to identify the specific amino acid residues in the protein that can be altered as claimed without further testing, where the polypeptide still retains phospholipase activity.

While the specification discloses isolated polypeptides having phospholipase activity consisting of the altered amino acid sequence of SEQ ID NO: 1 with the specific amino acid

alterations of variants 1-26 on pages 5-6, the specification, however, does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of the genus. The specification does not provide a correlation between any structure, other than the said variants 1-26, and phospholipase activity based on which those of ordinary skill in the art could predict which amino acids can vary from without losing the catalytic activity. Further, there is no art-recognized correlation between any structure, other than the said variants 1-26, and phospholipase activity based on which those of ordinary skill in the art could predict which amino acids can vary without losing the catalytic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 1 and still retain phospholipase activity.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional proteins having phospholipase activity. As such the disclosure of the above mentioned variants 1-26 having phospholipase activity, is insufficient to be representative of the attributes and features common to all the members of the claimed genus.

*Vas-Cath, Inc. v. Mahurkar,* 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the claimed genus.

8. Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide having phospholipase activity consisting of the altered amino acid sequence of SEQ ID NO: 1 with the specific amino acid alterations of variants 1-26 stated on pages 5-6 of the specification; **does not** reasonably provide enablement for any polypeptide having phospholipase activity comprising any amino acid sequence having at least at least 50%, 60%, 70%, 80%, 90%, 95%, and 98% sequence identity to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any polypeptide having phospholipase activity comprising any amino acid sequence having at least at least 50%, 60%, 70%, 80%, 90%, 95%, and 98% sequence identity to SEQ ID NO: 1.

The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the

factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships.

The specification provides guidance, prediction, and working examples for isolated polypeptides having phospholipase activity consisting of the altered amino acid sequence of SEQ ID NO: 1 with the specific amino acid alterations of variants 1-26 stated on pages 5-6 of the specification. However, the specification does not provide guidance, prediction, and working examples for making and/or using the invention as claimed.

The specification does not provide a correlation between any structure, other than the said variants 1-26, and phospholipase activity based on which those of ordinary skill in the art could predict which amino acids can vary from without losing the catalytic activity. Further, there is no art-recognized correlation between any structure, other than the said variants 1-26, and phospholipase activity based on which those of ordinary skill in the art could predict which amino acids can vary without losing the catalytic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 1 and still retain phospholipase activity.

Thus, one must perform an enormous amount of trial and error experimentation to search and screen for the claimed polypeptides from any biological source or synthesize the polypeptides and determine if the polypeptides still retain phospholipase activity. General teaching regarding screening and searching for the claimed invention using activity assays stated in the specification is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 6:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Patent Examiner
Art Unit 1652